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No. 06-1249

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IN THE

Supreme Court of the United States

WYETH,

Petitioner,

v.

DIANA LEVINE,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF THE STATE OF VERMONT

REPLY BRIEF

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LIST OF PARTIES

Petitioner's list of parties was set forth at page *ii* of its Petition for Writ of Certiorari, and there are no amendments to that statement.

CORPORATE DISCLOSURE STATEMENT

Petitioner's corporate disclosure statement was set forth at page *ii* of its Petition for Writ of Certiorari, and there are no amendments to that statement.

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1 Kenneth Culp Davis, *Administrative Law Treatise* § 5.09 (1958) 10

Respondent's Brief in Opposition ("BIO") fails to overcome the demonstration by Wyeth and supporting amici that the issues arising from the facts of this case warrant the Court's immediate review. Specifically, the federal preemption issues raised by Wyeth's Petition are of great doctrinal and practical importance, particularly given the deep-seated division of views reflected in the split Vermont Supreme Court opinion. Respondent has no substantial answer to these points, which call for a grant of the Petition under this Court's Rule 10(c).

Instead, Respondent seeks to undermine this case as a "vehicle" for presenting these issues by distorting relevant preemption precedent, misdescribing FDA's regulation of Phenergan, and mischaracterizing the nature of the Vermont Supreme Court's findings and the overall regulatory regime under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), including misrepresenting the effect of both the section 202 preemption clause in the Drug Amendments of 1962 and FDA's 2006 Preemption Preamble. *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006). Each of these contentions lacks merit.

I. Respondent Ignores The Deep Divisions In The Lower Courts Concerning The Preemptive Effect Of FDA's Labeling Judgments.

Respondent portrays a false uniformity in lower court decisions by claiming that "[n]o appellate court – federal or state – has ever held that the FDA's drug approval authority or its authority over drug labeling preempts a state-law tort suit[.]" BIO 13. Respondent conveniently ignores the California Supreme Court's decision in *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1 (Cal. 2004) (discussed at length in the Brief of Amicus Curiae Pharmaceutical Research and Manufacturers Association of America Supporting Petitioner 17-19 ("PhRMA Brief")). It also ignores a long line of federal appellate cases clearly endorsing conflict preemption to foreclose tort actions based on FDA's analogous Pre-Marketing Approval ("PMA") of medical devices. For example, the Third Circuit recently held that:

> Because the design of the HeartMate, the labeling and the instructions for its use, and the specification of the suture and its location when the HeartMate is implanted, as well as the other requirements imposed by the PMA, were the subject of extensive consideration by the FDA leading up to its PMA approval, any finding in [plaintiff] Horn's favor based on her general claims of negligence of defective design and manufacture – be it by a jury or a court – would . . . "stand as an obstacle to the accomplishment and execution of" the objective of the safety and effectiveness of the HeartMate specifically and would conflict with the federal requirements imposed by the PMA.

Horn v. Thoratec Corp., 376 F.3d 163, 169 (3d Cir. 2004) (citation omitted); *see also Riegel v. Medtronic, Inc.*, 451 F.3d 104, 122 (2d Cir. 2006), *cert. pending and Solicitor General's views invited*, 127 S. Ct. 575 (2006); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 798-99 (8th Cir. 2001) 'observing that any conflicting requirements sought by the plaintiff threatened "to interfere with . . . specific federal interest[s]" and were preempted); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 584 (5th Cir. 2001); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 226-27 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997).

Respondent also ignores the ongoing division of views stimulated in the lower courts by FDA's Preemption Preamble. *Compare In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. 05-1699, 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006) *with Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876 (E.D. Tex. 2005); *see also* Pet. for Writ of Cert. ("Pet.") 16-17. Far from being settled, this area of the law is in turmoil. Letting the issue of preemption under the FDCA continue to percolate through the lower courts could risk erroneous decisions in tens of thousands of pending cases. Pet. 13-14.

II. Respondent Misdescribes FDA's Regulation Of Phenergan.

Respondent erroneously argues that "Ms. Levine's recovery was *not* based on a labeling judgment different from a labeling judgment made by the FDA." BIO 14-15. Indeed,

Respondent contends that "use of the IV push method is not . . . even mentioned" on Phenergan's label, BIO 4, that FDA's consideration of Phenergan's labeling through 1987 "did not concern the method of administration of Phenergan in general, or the IV push method in particular," BIO 9, and that "no record evidence suggests that the FDA even considered the particular safety ramifications of the IV push method for Phenergan administration," BIO 17. These unsupported assertions, however, are belied by (a) the requirements of the FDCA, (b) Phenergan's FDA-approved label itself, and (c) the established administrative record of FDA's comprehensive evaluation of the safety issues arising from arterial exposure to Phenergan.

Since 1938 – long before Phenergan's approval – the FDCA has required FDA to find a drug to be "safe for use under the conditions prescribed, recommended or suggested in the proposed labeling thereof" before approving it for marketing. 21 U.S.C. § 355(d); *see also id.* § 355(e) (requiring FDA to withdraw drug from market where "new evidence . . . shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved"). Thus, FDA's approval of a prescription drug and its labeling establishes FDA's judgment that the methods of administration "prescribed, recommended or suggested" in that labeling permit safe use of the drug.

Despite Respondent's contrary claim that Phenergan's labeling does not mention IV push injection, BIO 4, the label's "Dosage and Administration" section expressly states that the "TUBEX® Sterile Cartridge-Needle Unit" injection apparatus disclosed in the labeling "is suitable for substances to be administered *intravenously or intramuscularly*" and specifically describes a method for "push" injection using that apparatus as follows: "Method of Administration is the same as with conventional syringe. Remove needle cover by grasping it securely, twist and pull. Introduce needle into patient, aspirate by pulling back slightly on the plunges, and inject." App. 168a (emphasis added). The label also expressly describes the increased efficacy of IV, as opposed to intramuscular, injection, App. 167a, states that intravenous administration "is well tolerated, but use of this route is not without some hazard,"

App. 168a, and makes clear that "deep intramuscular injection" is "[t]he preferred parenteral route of administration," App. 168a. It even expressly describes the hierarchy of *IV administration* options – *i.e.*, IV push injection versus IV drip – advising that "[w]hen used intravenously . . . it is preferable to inject through the tubing of an intravenous infusion set that is known to be functioning satisfactorily." App. 168a.

The administrative record of FDA's ongoing review of Phenergan likewise demonstrates that, contrary to Respondent's arguments, FDA and its Advisory Committee not only were well aware of the risks of arterial exposure but were the driving force behind many of Phenergan's labeling statements concerning those risks as well as the hierarchy of IV and other administration methods. *See, e.g.*, App. 147a (recommending preservation of warnings regarding intra-arterial injection); App. 148a (recommending addition of instruction that if Phenergan is administered intravenously, it should be "injected into a satisfactorily functioning intravenous set"); *see also* App. 142a, 143a, 151a, 152a, 153a, 162a. Thus, the record clearly demonstrates that FDA determined that Wyeth's label should include IV push injection as a less-preferred, but permissible, alternative. The crux of the present dispute is the conflict between that FDA determination and the imposition by Vermont's judicial process of a requirement that IV push injection be proscribed. *Compare* BIO 1 *with* Pet. 17.

III. Respondent Cannot Evade The Direct Collision Of Judgment Between FDA And Vermont.

Respondent attempts to avoid the diametric collision of federal and state judgment on the safety of IV push injection by pointing to the Vermont Supreme Court's conclusion that Wyeth failed to prove that FDA had considered, and would have rejected, a proposed label change to foreclose IV push injection. BIO 2, 14-15, 21. Above and beyond the fact that the Phenergan label itself, as well as the administrative record, establish that FDA had carefully considered the safety implications of IV and other forms of administration and devised a hierarchy of administration options, *see supra* Part II,

that argument is without merit. Even assuming that Wyeth would have had a basis for seeking such change, the Vermont Supreme Court, addressing preemption as a matter of law, App. 6a, committed a fundamental legal error by seeking to determine what FDA might have done if hypothetically presented with a proposed label change. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349-51 (2001) (shielding FDA decisional processes from state law intrusion). The Vermont Court's insistence that a conflict could be established only by a showing that Petitioner unsuccessfully sought FDA approval for the warning that Respondent advocated under Vermont law would produce the same disruption of regulatory relationships that this Court foreclosed in *Buckman*.

The error presented by Petitioner is not, as Respondent would have it, "an erroneous factual finding." *See* BIO 14-15, 21. Rather, that error lies in the legal standard for determining the federal-state conflict on which preemption is based. *See Steele v. Depuy Orthopaedics, Inc.*, 295 F. Supp. 2d 435, 446 (D.N.J. 2003) (explaining that "whether the FDA's approval of a PMA supplement imposes requirements on a particular device is a question of law to be determined by the Court, not a question of fact for the jury"). Under *Buckman*, that conflict must be assessed on the administrative record as it exists rather than on the basis of speculation whether the agency would or would not have modified it. *See Buckman*, 531 U.S. at 349-51.

Respondent also argues that Wyeth could have overcome FDA's judgment of record, and thus conformed to Vermont's standard of care, by unilaterally changing its label under FDA's "changes being effected," or "CBE," regulation. BIO 12, 24 (citing 21 C.F.R. § 314.70(c)(6)(iii)). But Respondent's defense of the Vermont Supreme Court's out-of-context reading of that regulation, App. 19a, flies in the face of FDA's comprehensive regulatory regime. Petitioner's interpretation, in contrast, accords with the overall FDCA framework and the weight of judicial authority, which limit the CBE regulation to exigent circumstances where "new information" on a drug necessitates an immediate labeling change. Pet. 19.

Respondent's reliance on 21 C.F.R. § 201.80(e), BIO 24-25, to suggest that FDA regulations mandated that Wyeth foreclose IV push injection only confirms Petitioner's analysis. Section 201.80(e) has both a temporal component (labeling to be revised "as soon as" there is an appropriate basis), and a substantive component ("reasonable evidence" of an associated hazard). At the time of Respondent's injury, FDA had been long aware of the risks of arterial exposure, had extensively regulated the statements on Phenergan's labeling concerning the hierarchy of administration options in light of those risks, and had even rejected a proposed warning change by Wyeth purporting to respond even more specifically to the "reasonable evidence" on arterial exposure in its possession. Respondent's contention effectively would impose the absurd requirement on Wyeth repeatedly to seek labeling changes for every conceivable permutation of language concerning a particular risk – even if FDA had known of that risk for decades and had previously rejected proposed changes designed to address that risk – and is clearly untenable. *See, e.g., Dowhal*, 88 P.3d at 10 (explaining that the "warning continues to be binding until the *new data* emerges and a change is requested" (emphasis added)); *McNellis ex rel De Angelis v. Pfizer, Inc.*, No. 05-1286, 2006 WL 2819046, at *6 (D.N.J. Sept. 29, 2006) (Section 201.80(e) is triggered "as soon as *new evidence* of a serious hazard exists." (emphasis added)).

In a further effort to avoid impossibility preemption, Respondent suggests that there can be no conflict generated by the legal duty imposed on Wyeth because Vermont "does not require Wyeth to alter its conduct but only to pay damages to Ms. Levine." BIO 25. Even apart from the fact that this contention contradicts the clear intention of the Vermont Supreme Court, App. 15a (concluding that "state common law duty may encourage departure from a label that the FDA has approved in great detail"), it misstates this Court's settled preemption jurisprudence. *See San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959) (explaining that "regulation can be as effectively exerted through an award of damages as through some form of preventive relief" and that "[t]he obligation to pay compensation can be, indeed is designed to

be, a potent method of governing conduct and controlling policy"); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521-22 (1992) (plurality opinion) (explaining that "since *Erie R. Co. v. Tompkins*" the Court has "recognized the phrase 'state law' to include common law as well as statutes and regulations.").[1]

IV. Respondent Cannot Evade Consideration Of Obstacle Conflict Preemption Under The FDCA Or The Degree Of Deference To Be Accorded FDA's Preamble.

Turning to obstacle preemption, Respondent recites, without providing any supporting analysis whatsoever, the Vermont Supreme Court's conclusions that the application of this strand of conflict preemption to prescription drug labeling cases is entirely foreclosed by section 202 of the Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962). BIO 25. It also agreed with the Vermont Court's holding that FDA's 2006 Preamble analysis of the obstructive effect of state tort judgments on its regulatory regime should be given no weight. BIO 26-28. Respondent again errs in both contentions.

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1. Respondent's reliance on *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005) for the proposition that no impossibility of compliance can arise from a conflict between a federal duty and a state common law tort duty is in error. BIO 25. In *Bates*, this Court interpreted the term "requirement" in a federal preemption clause barring States from imposing "requirements" that differed from analogous federal requirements. 544 U.S. at 443. While the Court explained that "requirements" should be determined by "an examination of the common law duty at issue," *id.* at 445, and that the lower court was wrong to blindly assume "that any event, such as a jury verdict, that might 'induce' a pesticide manufacturer to change its label should be viewed as a requirement," *id.* at 443, it was careful to explain that "the term 'requirements' in § 136v(b) reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties." *Id.* (citation omitted). Hence, the common-sense understanding that each statutory preemption clause must be reviewed to determine its reach does not in any way undermine the settled rule that federal law preempts any state law that conflicts, irrespective of whether the state law is a statute, regulation, or jury award. *See, e.g., Int'l Paper Co. v. Ouellette*, 479 U.S. 481, 494 (1987) ("[T]he application of Vermont [nuisance] law against IPC would allow respondents to circumvent the NPDES permit system, thereby upsetting the balance of public and private interests so carefully addressed by the Act.").

As explained in the Petition, the text and legislative history of section 202 foreclose field preemption but expressly preserve preemption claims in cases involving "direct and positive conflict[s]." Pet. 23-24. Congress's choice of the phrase "direct and positive conflict" – a phrase with well-accepted roots in obstacle preemption – is telling. Because of both Congress's preservation of obstacle preemption by its use of a phrase long associated with obstacle preemption claims and the statutory mandate to apply the "unless" clause in section 202, the courts are obligated to consider whether the duty imposed on Wyeth by Vermont law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" as implemented by FDA under the FDCA. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941); *see also Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 457 (2005) (Thomas, J., concurring in part, dissenting in part) (concluding that statutory preemption language applies as written without regard to any contrary presumption favoring state law). Where, as here, Vermont seeks to foreclose a treatment option that FDA has left open, Vermont law stands in "direct and positive" conflict with FDCA.[2] It simply defies logic to suggest that Congress, when it empowered FDA to protect the public health and safety, intended at the same time to allow state law to frustrate FDA in achieving that statutory objective.

Respondent's further efforts to support the Vermont Supreme Court's misguided decision to accord "no deference"

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2. Respondent's reliance on *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002), is misplaced. BIO 26. That case merely held that the Coast Guard's decision not to adopt a particular regulation could not be viewed as "the functional equivalent of a regulation prohibiting all States and their political subdivisions from adopting such a regulation." *Sprietsma*, 537 U.S. at 66. Moreover, the Solicitor General and counsel for the Coast Guard expressly had informed the Court that "the agency does not view the 1990 refusal to regulate or any subsequent regulatory actions by the Coast Guard as having any pre-emptive effect." *See id.* at 68. Here, FDA has affirmatively regulated every aspect of Phenergan's labeling – including IV injection in particular – since its introduction to the market in 1955. Pet. 6-9. Moreover, FDA specifically commanded Wyeth to retain a particular instruction concerning IV administration instead of permitting Wyeth to alter the instructions in a way that would further encourage IV drip administration over IV push administration. App. 160a-163a.

to FDA's Preemption Preamble, on grounds not reached by that court, App. 25a-26a, are similarly unpersuasive. BIO 26. Respondent creates and attacks a straw man by contending that FDA was seeking to enact a legislative rule in the Preamble. BIO 21-23. To the contrary, as explained in the Petition, the Preamble sets forth FDA's longstanding construction of its own regulations and the impact of state-imposed duties on the accomplishment of FDA's regulatory purposes. Pet. 27-29. FDA's interpretation, addressing the FDCA, clearly governs conflicting duties arising before 2006 as well as thereafter.

FDA's publication readily falls within the definition of an interpretive rule. *See, e.g., United Techs. Corp. v. EPA*, 821 F.2d 714, 718 (D.C. Cir. 1987) ("An interpretive rule simply states what the administrative agency thinks the [underlying] statute means, and only reminds affected parties of existing duties." (internal quotations and citations omitted) (alteration in original)).[3] Unlike legislative rules, interpretive rules do not raise retroactivity concerns. *See, e.g., Griffon v. U.S. Dep't of Health & Human Servs.*, 802 F.2d 146, 151 (5th Cir. 1986)

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3. As an interpretive rule, the Preamble also is not subject to the formality of "notice and comment" that Respondent seeks to invoke. BIO 27. Indeed, deference has been afforded to interpretative rules of varying formality. *See, e.g., Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000); *Auer v. Robbins*, 519 U.S. 452, 453 (1997). And, with respect to FDA, this Court has made clear that its expert judgments are entitled to particular deference. *See, e.g., Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 653-54 (1973) ("The determination whether a drug is . . . safe and effective" is "peculiarly suited to initial determination by the FDA."). Respondent's further argument that FDA has taken inconsistent interpretive positions on preemption is equally mistaken. Respondent seizes on a 2000 FDA statement that prescription drug labeling "does not preempt State law." BIO 8 (quoting 65 Fed. Reg. 81,802, 81,103 (2000)). But this was merely a statement recognizing that field preemption does not apply – it was not an indication that the States are free to override specific FDA determinations to create direct and positive federal-state conflicts. To the contrary, FDA had consistently maintained, both before and after 2000, that state-law standards of care that differ from federal labeling judgments pose an obstacle to the federal regime. *See generally* Brief for Amicus Curiae The United States of America, *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006) (No. 05-05500).

("Interpretative rules do not require notice and comment rulemaking, 5 U.S.C. § 553(b)(3)(A), and cannot be retroactive because they effectuate the intent of the statute."); *Appalachian States Low-Level Radioactive Waste Comm'n v. O'Leary*, 93 F.3d 103, 113 (3d Cir. 1996) ("[R]etroactivity concerns are irrelevant to this case. The Secretary's ruling was interpretive. It therefore did not alter existing rights or obligations; it merely clarified what those existing rights and obligations had always been."); *see also* 1 Kenneth Culp Davis, *Administrative Law Treatise* § 5.09 (1958).

Recognizing the persuasiveness of FDA's Preamble and the agency's expertise in assessing how the public health would be affected by imposing state-created duties on manufacturers, the better-reasoned court decisions have accorded compelling weight to FDA's analysis. Pet. 28-30. This Court should review this case and support that sound result.

CONCLUSION

For the foregoing reasons and for the reasons set forth in the petition, this Court should grant the petition for writ of certiorari.

Respectfully submitted,

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